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Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD

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14. ABSTRACT This study is a randomized trial of a hybrid treatment for Iraq and Afghanistan Veterans with a history of mild to moderate TBI (mTBI) and PTSD. Emotional symptoms are likely a main cause of the persistence of post-concussive symptoms while thinking problems and emotional control problems associated with mTBI can impede recovery from PTSD. However, there is no PTSD treatment specifically designed to accommodate the difficulties with attention, memory, and problem solving that patients with TBI may have. Therefore, this study integrates therapeutic approaches and tests a modification of cognitive processing therapy (CPT), an empirically supported treatment for PTSD, in which CPT is enhanced with compensatory cognitive rehabilitation principles. The enhanced CPT, called SMART-CPT is being compared to standard CPT in a group of Iraq and Afghanistan Veterans with a history of both mTBI and PTSD. Half of the participants are randomly assigned to receive standard CPT and half to receive SMART-CPT. This year was dedicated recruitment, enrollment, and treatment, with 43 Veterans enrolled and 12 who have completed all treatment sessions, to date.					
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INTRODUCTION:

This study focuses on helping Iraq and Afghanistan Veterans who have a history of mild to moderate traumatic brain injury (TBI) and posttraumatic stress disorder (PTSD) benefit fully from interventions for both conditions. PTSD and TBI occur together frequently in Iraq and Afghanistan Veterans, a combination of conditions which often complicates recovery from either condition. Emotional symptoms are likely a main cause of the persistence of post-concussive symptoms while thinking problems and emotional control problems associated with mild to moderate TBI can impede recovery from PTSD. Prior research has shown that cognitive rehabilitation programs that focus on teaching about what is typical after a head injury, providing people with expectation of positive recovery, and teaching strategies that allow individuals to compensate for their cognitive deficits are effective for treating the thinking symptoms resulting from mild to moderate TBI. These practice standards have been organized into a manualized treatment, Cognitive Symptom Management and Rehabilitation Therapy (CogSMART), which teaches veterans ways to compensate for cognitive difficulties. Psychotherapies that focus on changing thoughts and behaviors related to a traumatic event, such as Cognitive Processing Therapy (CPT), are effective treatments for PTSD and are the standard of care for treatment of the disorder. However, there is no PTSD treatment specifically designed to accommodate the difficulties with attention, memory, and problem solving that patients with TBI may have. Therefore, this study integrates therapeutic approaches and tests a modification of CPT in which CPT is enhanced with compensatory cognitive rehabilitation principles detailed in CogSMART. The enhanced CPT, called SMART-CPT will be compared to standard CPT in a group of Iraq and Afghanistan Veterans with a history of both mild to moderate TBI and PTSD. Half of the participants will be randomly assigned to receive standard CPT and half to receive SMART-CPT.

BODY:

September 15, 2013 to September 14, 2014 was the third fiscal year of the Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD study. The focus in the third fiscal year was on recruitment, enrollment, assessment, and treatment.

The following are accomplishments as outlined in the Statement of Work:

Task 1. Study Start Up, Months 1-12: Complete, see prior annual report.

Task 2. Recruitment, Enrollment and Treatment and Assessment, months 13-40:

2a. Ongoing recruitment of participants:

In the third fiscal year of this study, the study coordinator has attended meetings in VA-based TBI and PTSD treatment clinics and has been in frequent contact with other study coordinators to facilitate study recruitment. We have also contacted our local Vet Centers as additional recruitment avenues and disseminated study brochures more widely to other relevant clinics within the VA (e.g., Member Services, Polytrauma, Social Work). The study coordinator has also responded to a steady flow of referrals from clinical providers within the PTSD clinics

in the La Jolla, Mission Valley and Oceanside VA locations. In addition, the study coordinator was in contact with student Veteran resource centers at local colleges and universities and distributed study brochures there as well.

The tables below depict recruitment efforts for the third fiscal year as well as recruitment to date. ‘Pending referrals’ are typically referred individuals with whom we have ongoing efforts to contact or who have expressed interest in enrolling but need to wait for medication stabilization or other scheduling issues.

Recruitment in third fiscal year:

Total Referrals	Enrolled	Pending	Declined/ Do not qualify
120	31	15	74

Recruitment to Date:

Total Referrals	Enrolled	Pending	Declined/ Do not qualify
233	69	15	149

2b. Treatment:

Of the 31 participants enrolled in the third fiscal year, 25 participants have started treatment. To date, 35 participants have been randomized to the SMART-CPT condition and 34 to the standard CPT treatment group. To date, 16 participants have completed the study, including all treatments and assessment sessions (including extended post-treatment assessment). Thirty-four participants have completed the 12 therapy sessions. Overall, 44% of participants have not continued treatment to the completion of the study. Fidelity checks of therapy sessions are proceeding on schedule and Dr. Boyd, the study psychologist, continues to meet weekly with Dr. Rodgers for supervision regarding the study treatments. We have not had a serious adverse event in the third year of this project.

2c. Assessment:

In the third fiscal year we have completed 30 pre-treatment assessments, 13 post-treatment assessments, and two extended follow-up assessments. To date, 67 enrolled participants have undergone the pre-treatment assessment consisting of neuropsychological, mood, and symptom ratings. Thirty participants have undergone the post-treatment assessment, and 16 have completed the extended follow-up assessment and fully completed the study. All assessments continue to be double-scored and double-entered into the database to insure accuracy in administration, scoring, and data entry and that any errors are not perpetuated.

Preliminary data analysis to determine initial response to and tolerability of treatment reveals that those Veterans in the standard CPT group had starting PCL scores of 59.7 and ending PCL scores of 38.58 (average change of 21 points). Veterans in the SMART-CPT group had starting PCL scores of 57.31 and ending PCL scores of 40.59 (average change of 17 points). This data establishes that the treatment results in clinically significant change in PTSD symptoms and that adding cognitive rehabilitation principles to standard CPT does not ‘dilute’ the treatment for PTSD in any way. The non-completion rate is equivalent between groups,

however, of those who do not complete the treatment, the SMART-CPT group completes significantly more sessions before dropping out than those from the CPT group (5.1 sessions vs. 2.0 sessions; $t=-2.58$, $p=.015$). Because one concern regarding using CPT in populations with cognitive complaints is early drop-out, these preliminary results are encouraging and suggest that the hybrid SMART-CPT approach is able to enhance treatment session completion in comorbid PTSD and TBI.

KEY RESEARCH ACCOMPLISHMENTS:

- All regulatory approvals were renewed and are current and up to date.
- 69 Veterans have been enrolled in the trial to date
- 30 Veterans have completed baseline assessment, therapy, and post-therapy assessment
- 16 Veterans have completed all components of the study (which includes the extended follow-up)

REPORTABLE OUTCOMES:

- The International Neuropsychological Society 42nd Annual Meeting was held February 12-15, 2014 in Seattle, Washington where Dr. Jak and graduate student researcher, Sarah Jurick, presented clinically derived data on cognitive rehabilitation and neurobehavioral symptoms in Veterans with a history of mild to moderate TBI. They also acquired continuing education regarding neuropsychological assessment, cognitive rehabilitation, and TBI, which will inform the present study as well as future directions.
- Dr. Jak was invited by Dr. Krawczyk to present at the University of Texas at Dallas Center for Brain Health colloquium series on “Innovations in Assessment and Treatment of Post-concussive Symptoms in Veterans” on May 30, 2014. This presentation drew heavily from the work funded by this award.
- Dr. Jak was invited to speak at the National Association of Drug Court Professional/Vet Court Con Annual Training Conference, Anaheim, CA on “Traumatic Brain Injury” on May 28, 2014. This presentation drew heavily from the work funded by this award.
- As requested/required, Dr. Jak presented to the Military Operational Medicine Research Program Concussion Research IPR July 21-22, 2014, Ft. Detrick, MD.
- Dr. Jak was invited by Division 40 and 47 of the American Psychological Association (APA) to contribute to a symposium for the APA Convention in August 2014. The 2-hour symposium entitled “Active Recovery Strategies for mTBI/Concussion: Interdisciplinary Evidence-based Treatments and Rehabilitation”, was presented with Anthony Kontos, Kim Gorgens, and Jay Uomoto. Dr. Jak’s portion of the symposium focused on SMART-CPT and cognitive rehabilitation for Veteran’s with comorbid TBI and PTSD.

CONCLUSION:

In summary, “Enhanced Cognitive Rehabilitation to Treat Comorbid TBI and PTSD”, is proceeding generally on schedule and most tasks detailed in the statement of work, including maintaining regulatory approvals, recruitment efforts, assessments, and treatment are proceeding as planned; our drop-out rate is higher than anticipated, however. 69 Veterans have enrolled in the study to date, 31 of them in this reporting period. In the third year, we have not encountered any serious adverse events. Preliminary examination of the data revealed clinically significant reductions in PTSD symptoms in both treatment groups. Of those who did drop out of treatment, the SMART-CPT group completed significantly more sessions before dropping out than those from the CPT group. Work supported by this award has also led to six presentations this fiscal year.

While our recruitment and enrollment has been consistent with our proposed rate in the SOW, we have experienced a higher than expected attrition rate (44%). Although high, it is nonetheless well aligned with dropout rates reported in the literature for OEF/OIF Veterans, in particular (e.g., Chard, et al., 2010). It also reflects difficulties with treatment dropout noted by an Institute of Medicine Report (Treatment for Posttraumatic Stress Disorder in Military and Veteran Populations: Initial Assessment, 2012) that may be related, in part, to high rates of comorbidities in the target population as well as trauma-related avoidance. We have targeted a representative treatment seeking sample by including those individuals with relatively recent sobriety and mental health comorbidities, and do not exclude participants based solely on the presence of suicidal ideation. This results in a more challenging, though realistic, treatment sample. All of these factors are likely contributing to the attrition rate and are concerns we are actively working to overcome. Although the dropout rate is not different between the two treatment conditions in this study, those in the experimental SMART-CPT arm, which targets comorbid post-concussive symptoms, continue to remain in treatment longer (average 5 sessions) than those in standard CPT (average 2 sessions), suggesting that concurrently addressing comorbidities can improve treatment adherence. Because we are otherwise on schedule with recruitment and have sufficient budgetary funds, we are prepared to over-recruit and over-enroll as needed over the next fiscal year to meet our desired usable sample of 72 participants. Tasks detailed in the SOW for the fourth fiscal year will be delayed and we will likely formally request a no cost extension of this project for one year to aid in meeting our final sample size; fiscal year 4 tasks as detailed in the SOW would then be completed in fiscal year 5.

REFERENCES:

None at this time.

APPENDICES:

None at this time.